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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,623	09/14/2000	Dennis Cherok	D0188/7125	8712

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,623

Applicant(s)

CHEROK ET AL

Examiner

William H. Matthews (Howie)

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 14-21 and 29-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-21 and 29-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7, 12.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The Examiner has obtained copies of the references listed in the previous information disclosure statement #7 filed February 11, 2002. A copy of the signed PTO-1449 is enclosed.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 14-17, 20, 21, 37-39, and 42-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Eldridge et al. WO 98/49967.

Eldridge et al. discloses an implantable device for repairing tissue or muscle defects comprising a layer of repair fabric made of polypropylene having interstices, barrier layer made of PTFE that covers the entire layer of repair fabric, stitches connecting both layers, and a peripheral barrier that inhibits adhesions with tissue. The peripheral barrier is formed by melting the middle layer of the repair fabric to the PTFE barrier layer. Therefore a portion of the outer peripheral edge has been altered to render this edge adhesion resistant. Note that the entire surface of the middle layer of the implant is melted to the PTFE layer and resolidified which encompasses the specific limitations of claims 4, 37, and 42 regarding a peripheral edge or outer margin being melted and resolidified (see page 5, lines 3-13).

Art Unit: 3738

With regard to claims 16, 17 and 44, stitches are described for attaching the barrier layer and fabric layer to tissue wherein the stitches are disposed slightly inward of the edge (see lines 1-5 of page 8 as well as lines 11-12 of page 7). Therefore the repair fabric layer and barrier layer are stitched together at a location inward of the peripheral edge.

With regard to claim 39, an irregular or non-uniform thickness is disclosed in page 5, lines 7-9. Also note that the fact that the fabric layer is porous fulfills the limitation of a non-uniform thickness.

3. Claims 54-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Gianturco US PN 5,258,000.

Gianturco discloses a tissue repair prosthesis in figures 3-4 comprising a polypropylene layer of repair fabric (13), GORETEX (ePTFE) barrier layer (16), and a plurality of stitches (17) joining the barrier and repair fabric layers and to create a bite region for added strength and support (lines 18-22 of col. 5). Note that the claims do not recite that the entire stitch line be disposed completely inward of the outer peripheral edge. Lines 15-18 disclose that the barrier layer and repair fabric layer are heat sealed which inherently involves some degree of melting and re-solidifying to render at least a portion of the outer peripheral edge substantially impervious to tissue ingrowth.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 19, 45-48, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above in view of Sharber et al. US PN 6,075,180.

Eldridge et al. meets the limitations of claims 18, 19, and 45 but lacks the express disclosure of using PTFE stitches or sutures. Sharber et al. teaches the well-known use of PTFE for suture material because of PTFE's low reactivity in the body.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute PTFE sutures, as taught by Sharber et al., for the sutures disclosed by Eldridge et al. in order to provide a material unlikely to react negatively in the body.

6. Claims 49-52 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above in view of Sharber et al. US PN 6,075,180 as applied to claims 18, 19, 45-48, and 53 above and in further view of Darois et al. US PN 6,258,124.

Neither Eldridge et al. or Sharber et al. expressly disclose the particular features of the stitch pattern of claims 49-52 or combination of bite region and stitches of claims 54-59. However, Darois et al. teaches in Figure 1 a repair patch having a plurality of

Art Unit: 3738

connecting stitches following a predetermined shape of the outer perimeter, as well as a plurality of stitches arranged in a concentric pattern wherein at least one series of stitches is disposed slightly inward of the peripheral edge. Furthermore, with regard to claims 54-59, the outer margin is reinforced by the stitches to form a bite region between the outermost stitch series and outer peripheral edge. Lines 32-59 of column 4 teach that the stitch pattern is beneficial to prevent separation of the barrier layer and fabric layer after implantation.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention disclosed by Eldridge et al. to include the PTFE stitches as taught by Sharber et al. and furthermore, use the concentric pattern as taught by Darois et al. in order to securely join the fabric layer and barrier layer to prevent separation after implantation.

7. Claims 5-7, 29-36, and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. WO 98/49967 as applied to claims 1-4, 14-17, 20, 21, 37-39, and 42-44 above and in further view of Pajotin et al. US PN 6,368,541.

Eldridge et al. meets the limitations of claims 5-7, 29-36, and 40-41 except Eldridge et al. does not specifically disclose an outwardly tapered peripheral barrier. However, Pajotin et al. teaches an implantable prosthesis for repairing a muscle or tissue defect having a tapered peripheral edge to assist implantation (see figure 2 and line 62 of column 1 through line 2 of column 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Eldridge et al. to include a tapered edge as taught by Pajotin et al. in order to assist implantation of the device into the body.

Response to Arguments

7. Applicant's arguments filed September 3, 2002 have been fully considered but they are not persuasive.

Restriction Requirement

8. Examiner has reconsidered the restriction requirement, but the requirement still stands for reasons set forth in the restriction requirement mailed November 8, 2001.

Claim Rejections under 102(b)

9. With regard to claim 1, Applicant contends that fusing of the middle layer to the barrier layer does not result in a peripheral barrier. As discussed and recorded in the attached interview summary, the Examiner contends that among other barriers formed from the fusing process, a peripheral barrier is formed. This peripheral barrier does not cover the entire thickness of the outer peripheral edge of the layer of repair fabric, but does indeed fulfill the limitations of the peripheral barrier in claim 1.

10. With regard to claim 37, Applicant contends that the inner portion of the sheet would not be tissue infiltratable. Examiner disagrees. By fusing the middle layer, only the middle layer is not tissue infiltratable or susceptible to adhesions. This middle layer forms a portion of the outer peripheral edge and fulfills the claim limitations. The outermost layer of the repair fabric layer is still susceptible to tissue ingrowth.

Claim rejections under 103(a)

11. With regard to claims 18,19,45-48, and 53, Applicant contends that one of ordinary skill in the art would be directed away from the combination of Eldridge and Sharber. However, Sharber, as confirmed by Applicant, teaches "PTFE has a long history of use as an implantable material because it is one of the least reactive materials known. One known application for PTFE identified by Sharber is sutures." To further support Applicant's argument, Applicant states that Eldridge doesn't even teach the stitches joining the barrier layer and repair fabric layer as claimed. However, the Examiner has previously shown that lines 1-5 of page 8 disclose sutures stitched through both barrier and repair fabric layers during the implantation step. Therefore, since it is well known in the art to prefer PTFE suture as taught by Sharber and Eldridge discloses the step of suturing the layers of the device to tissue, it would have been obvious to combine the references to achieve the claimed invention.

12. With regard to claims 49-52 (note that arguments pertaining to claims 54-59 are moot in view of the new grounds of rejection), issues pertaining to the use of the PTFE sutures taught by Sharber are discussed above. Applicant further contends that it would not have been obvious to utilize the concentric stitch patterns taught by Darois because the barrier layer and repair fabric layer are already attached. However, as previously described, the motivation to provide extra support exists in order to prevent possible separation after implantation.

13. With regard to claim 29, Applicant contends that it would not have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of

Art Unit: 3738

Pajotin with Eldridge to arrive at a device having a tapered edge because Pajotin apparently doesn't teach a tapered edge. Applicant contends that the figure that appears to show a tapered prosthesis is merely a three-dimensional representation of a flat prosthesis. The Examiner respectfully disagrees. Lines 62-65 of column 1, along with figure 2, clearly describe a prosthesis having tapered edges and reasons for doing so, i.e. to more easily implant the prosthesis through an tissue layers. Applicant's final argument is based on the fact that a surgeon may cut the Eldridge prosthesis to size during the surgery. Although this is a possibility for the Eldridge prosthesis, Eldridge does not disclose the device to be used solely in this manner. The reference to lines 17-18 of page 4 seems more to contemplate if cutting occurs rather than suggesting that cutting should occur. In any event, it would seem favorable to one of ordinary skill in the art at the time of the invention to have a sheet with tapered edges so that, should the surgeon cut the sheet to size, at least some edges would be tapered to assist in the implantation step. For example, cutting the sheet in half would result in three tapered edges.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3738

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

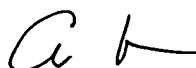
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

November 15, 2002



CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700